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Does a Personalized Health Portal for Diabetes Retinal
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14. ABSTRACT The transtheoretical model (TTM) of behavior change has been used successfully to describe explain and predict clinical outcomes in patients with type 2 diabetes (T2D) exposed to various educational interventions. The personalized health portal allows patients to remotely view their retinal images and other related health educational information on their own time. Due to the validity of survey items, this proposal will be focusing on daily self-management, smoking, exercise and carbohydrate counting for type 2 diabetic patients. This study hypothesizes that individuals with T2D who are in the precontemplation, contemplation, or preparation (early) stages for regular self-management, exercise, smoking and carbohydrate counting and who view their own retinal images via a web portal as a part of diabetes ophthalmologic screening will progress to a higher stage of change, increase their pros of changing, decrease their cons of changing, and increase self-efficacy in managing their symptoms.					
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Introduction

Diabetes is a serious health problem in the United States, according to the Center for Disease Control and Prevention (CDC), *National diabetes Fact Sheet, 2007*, an estimated 23.6 million children and adults have the disease; 5.7 million of whom are unaware of their condition. In addition, it is estimated that 57 million adults have pre-diabetic conditions, which is determined by blood glucose levels higher than normal. The CDC calculates health costs related to this disease total approximately \$174 billion per year. Over the last 10 years, the rate of newly diagnosed cases has increased more than 90 percent, with over 1.6 million new cases of diabetes diagnosed in adults every year in the U.S. (2008). In Hawai'i, data shows that there is an estimated 72,000 to 100,000 people that have diabetes, including 25,000 who remain undiagnosed, disproportionately affecting native Hawai'ians, Asian Americans, and Pacific Islanders (Hirokawa et al., 2004). Long term complications related to diabetes include diabetic eye disease, nerve damage (neuropathy), heart disease, stroke, kidney failure, and peripheral vascular disease, which can result in amputations and premature death. Diabetes is the seventh leading cause of death in the US (Centers for Disease Control and Prevention, 2008).

Management of patients with diabetes represents an enormous cost to the military health care system (Pogach et al., 2004). The prevalence of these conditions increases with age, and is particularly high among retirees and dependents. The incidence of T2D in the U.S. military is higher than that of the civilian population (1.9 vs. 1.6 cases per 1,000 person years)(Paris et al., 2001), even though height and weight standards are often rigorously enforced. Members of the military who become diabetic while serving on active duty face possible discharge. Although not all diabetic patients are discharged from the Army, the potential loss of personnel is troublesome. In addition, military personnel and their dependents affected by diabetes may require specialty consultation or medical interventions not available locally may need to travel long distances for such services. This travel interrupts a service person's regular duties, removes the person from his position of military readiness, and places the burden of travel expense and medical care on military resources

Diabetic eye disease, which affects both type 1 and type 2 diabetic patients, includes diabetic retinopathy (DR), cataracts and glaucoma. The most common occurrence of the three is diabetic retinopathy, which affects 40–45% of all those diagnosed with diabetes. There are four stages of DR: mild, moderate, severe and proliferative; the latter of which, if left untreated can result in severe blurred vision or vision loss. DR is the leading cause of adult blindness in the United States (National Eye Institute National Institutes of Health, 2010a) and has been shown to be present in nearly all people diagnosed with diabetes for a duration of more than 20 years (Aiello, Cahill, & Wong, 2001). A complication of DR is diabetic macular edema (DME), which is a swelling of the retina. This can occur at any stage of DR without symptoms. DME affects approximate 10% of all diabetic patients and can be diagnosed with eye examinations; yet, left untreated, DME can result in moderate vision loss (Cavallerano, 2005).

Typically, there are no early warning signs of DR. However, eye examinations, which are the standard of care for diabetic patients, can detect the disease in its early stages. Despite that yearly eye exams are recommended for all those diagnosed with diabetes, the primary reason for vision loss due to DR is the failure to have regular eye examinations (National Eye Institute National Institutes of Health, 2010b). Studies have shown that only 50-60% of diabetic patients actually have eye exams performed (Lee, Feldman, Ostermann, Brown, & Sloan, 2003). Perceived barriers to regular eye exams include cost, misconceptions that eye exams are unnecessary, and access to care (Hartnett, Key, Loyacano, Horswell, & Desalvo, 2005).

The purpose of this proposal is to use the transtheoretical framework to describe changes in behavior with a type 2 diabetic population when shown their digital retinal images and given access to a personal health portal (PHP) website. The transtheoretical model (TTM) is one of the leading behavior change models used both in research and clinical practice (Glanz, Rimer, & Viswanath, 2008). The constructs and variables were developed using a comparative analysis of existing theories in behavior change (Prochaska, Redding, & Evers, 2008). Retinal imaging uses cameras to take high-resolution pictures of the retina. This helps detect and manage retinal disorders that can lead to vision loss or blindness. The PHP allows the patients to remotely view their retinal images and other related health educational information on their own time. Due to the validity of survey items; this proposal will be focusing on daily self-management, exercise, smoking and carbohydrate counting for patients diagnosed with type 2 diabetes (T2D).

Body

The following are a summary of activities during this period.

Task A. Comprehensive Disease Management Program (CDMP) and retinal imaging implementation – 75% complete

Task A.1. Configure CDMP and workflow for the proposed clinical site – 75% complete

- a. CDMP has been configured for this study. In order for a complete and thorough interpretation and recommendation for treatment, the image reader must have certain medical information about each patient, i.e., laboratory values, blood pressure, etc. Thus, it has been determined that CDMP must be integrated with NextGen, the electronic medical record used by Waianae Coast Comprehensive Health Center (WCCHC). This integration would provide the most efficient and accurate method of obtaining that medical information and providing it to the image reader.

Estenda Solutions, Inc. will perform all the technical work for the CDMP/NextGen integration with the exception of software quality assurance prior to full implementation. John Williams (Chief Information Officer, WCCHC), has agreed to provide Estenda Solutions with a test database for software development. Several meetings were held to discuss the requirements for the integration. Thus the implementation requirements have been determined and integration has been initiated.

Task A.2. Configure CDMP as a personal health portal capable of displaying and presenting retinal images to patients via the web portal technology – 75% complete

- a. The patient portal prototype has been developed (see Attachment 1 for screen shot). The patient portal will allow the patient to see their image diagnosis reports and view their retinal images. The home page for the patient portal will be customized for this study.
- b. The educational component prototype has been developed. Educational content included will be: Information on diabetic eye disease, how diabetes affects vision, interpretation of retinal images, and how to prevent vision loss from diabetes. The educational website and educational content are under review by both research and clinical professionals (see Attachment 2 for screen shot). Several experts, other than the Principal and Co-Investigators, have agreed to review the content, this includes the following University of Hawaii professors and related professionals: Martha Crosby, PhD (Professor and Chair of Department of Information and Computer Sciences), Curtis Ikehara, PhD (Assistant Professor in Department of Information and Computer Sciences), Marie Iding, PhD (Professor in Department of Educational Psychology), Marjorie Mau, MD (Endocrinologist and Professor in Department of Native Hawaiian Health), Dee-Ann Carpenter, MD (Internist, Professor in Department of Native Hawaiian Health), and Constance Cox, MD (Ophthalmologist, Queen's Medical Center).

Task B. Conduct randomized control trial - 48% complete

- a. Several meetings were conducted to discuss and refine the study design. It was decided that a control group is not needed, since this is NOT an intervention study.

- These changes do not alter the outcomes and will not invalidate, but improve, the scientific merit and deliverables of the funding.
- b. Also, we have added the component of three focus groups, which will be conducted with select subjects that represent the spectrum of results. Specifically, the groups will be formed with subjects that had success in the program and those that did not show any behavior change. Group discussion will be audio taped, in addition to the recording of field notes. Information on the group's perceptions and opinions will be discussed. This can potentially identify the mechanisms of behavior change, as a result of the retinal imaging intervention.
 - c. We hope to start entering [patients in February 2011](#).

Task B.2. Complete all appropriate procedures with institutional review boards – 95% complete

- a. Approval for UH is in progress. Initial approval from local UH IRB has been obtained, however modification was requested due to changes in original protocol, this included refining of surveys and adding the focus groups. The office of Research Protections, Human Research Protection Office (HRPO) has approved this protocol for the Waianae site, which includes these modifications. Once changes have been approved by UH, the approval letter will be sent to HRPO for the government approval. Once this is achieved, we will have IRB approval for both UH and Waianae sites. [The following is a timeline for submissions and approvals thus far.](#)
 - B.2.a.1. [University of Hawaii Committee on Human Studies \(UH CHS\)](#)
 - B.2.a.1.1. [23 February 2010, application submitted to UH CHS](#)
 - B.2.a.1.2. [3 March 2010, UH CHS responded with comments and questions](#)
 - B.2.a.1.3. [4 March 2010, We responded to comments and questions](#)
 - B.2.a.1.4. [4 April 2010, received approval letter from UH CHS](#)
 - B.2.a.1.5. [18 August 2010, sent modification request to UH CHS \(note this was submitted AFTER approval from WCCHC was received\).](#)
 - B.2.a.2. [Waianae Comprehensive Coast Health Center](#)
 - B.2.a.2.1. [8 February 2010, sent IRB application](#)
 - B.2.a.2.2. [17 February 2010, WCCHC requested documents](#)
 - B.2.a.2.3. [4 March 2010, responded with requested information](#)
 - B.2.a.2.4. [5 March 2010, WCCHC requested additional information](#)
 - B.2.a.2.5. [5 March 2010, responded with requested information](#)
 - B.2.a.2.6. [10 March 2010, WCCHC requested additional information](#)
 - B.2.a.2.7. [2 April 2010, WCCHC approved contingent upon revisions](#)
 - B.2.a.2.8. [21 July 2010, responded with additional revisions \(time gap reflects re-evaluation of methodology, with minor changes submitted\)](#)
 - B.2.a.2.9. [21 July 2010, WCCHC requested additional information](#)
 - B.2.a.2.10. [10 August 2010, responded with requested revisions](#)
 - B.2.a.2.11. [11 August 2010, WCCHC approval letter received](#)
 - B.2.a.3. [Human Research Protection Office \(HRPO\), Office of Research Protections \(ORP\), US Army Medical Research and Materiel Command \(USAMRMC\)](#)
 - B.2.a.3.1. [14 May 2010, IRB protocol submitted for pre-review](#)
 - B.2.a.3.2. [17 May 2010, received requested changes](#)
 - B.2.a.3.3. [15 June 2010, sent back with revisions](#)
 - B.2.a.3.4. [11 August 2010, sent WCCHC approval letter](#)

Task B.3. Conduct training. Train the imager in protocol administration– this task will be completed upon completion of IRB process, educational web materials, and the integration of CDMP with NextGen. – 0% complete

Task B.4. Conduct intervention and data collection– this task will be completed upon completion of IRB process, educational web materials, and the integration of CDMP with NextGen. – 0% complete

Task B.5. Analyze data, interpret results, and prepare report – this task will be completed upon completion of the patient evaluation. – 0% complete

Key Research Accomplishments

Task A. Comprehensive Disease Management Program (CDMP) and retinal imaging implementation

Task A.1. Configure CDMP and workflow for the proposed clinical site

- a. CDMP has been configured for the PHP study, this task has been completed.

Task A.2. Configure CDMP as a personal health portal capable of displaying and presenting retinal images to patients via the web portal technology

- a. Patient portal mockup completed.
- b. Educational website mockup completed.

Task B. Conduct randomized control trial

Task B.1. Complete all appropriate procedures with institutional review boards

- a. The office of Research Protections, Human Research Protection Office has approved this protocol for the Waianae site.
- b. HRPO approval for UH pending modification approval from UH IRB.

Conclusions

For this study, the transtheoretical model was chosen to examine behavior change when patients diagnosed with type 2 diabetes are exposed to their retinal images and related eye disease information. The TTM is one of the most widely used models of health behavior and is easily applied to many areas in health behavior. The TTM was designed to be generalizable across a wide variety of populations and behaviors (Prochaska et al., 1994). TTM also used intuitive logic in assessing the constructs, utilizing the stage of health behavior change as the main construct, versus cognitive variables such as perceived risk or barriers, in which the other earlier theories revolved. The focus of the TTM is on individual change, versus interpersonal or community models. Despite that there may be other theories that are applicable to this study's purpose, the TTM was chosen due to the wide use in diabetes and individual behavior focus.

Based on a literature search (using Academic Search Premier, Medline and Psychology and Behavioral Science collection databases; key words included diabetes, health behavior theory, retinal imaging, retinopathy, teleretinal imaging, as keywords; date from 1997 through 2009; conducted March 2010) no published articles were found that prospectively examine digital retinal imaging and diabetes self-management and other related health outcomes. There is one retrospective study that looked at patient clinical outcomes and teleretinal imaging. This study took place at the Joslin Diabetes Center (Harvard Medical School) (n = 13,752). Results demonstrated a relationship between patients that received teleretinal imaging and improved HbA1c, LDL and systolic blood pressure over time (2 year span), as well as improved adherence to subsequent eye care (Fonda et al., 2007b).

In this study, we hope to demonstrate that personalization of health information over the Internet can have a positive impact on health outcomes, specifically; access to personalized digital retinal images can impact a person's health behavior as it relates to their diabetes condition. Due to advances in technology, image acquisition of the retina with the eye care system is now possible using low light levels; this eliminates the need for pharmacological dilation of the pupil, making the process more comfortable and less intrusive for the patient. Thus this provides a platform that is more readily available, accessible and comfortable for the patient. Importantly, the system allows images to be available for viewing by clinicians and patients in the workplace and at home, with the goal of positively impacting healthy behaviors (Fonda et al., 2007a; Bursell et al., 2001).

Of significance to the military is the realization of substantial cost savings for treating chronic disease. The cost of treating the long-term complications of diabetes consumes a major part of the Veterans Administration medical budget and is an important component of the Department of Defense expenditures. The Veterans Health Administration identifies diabetes as a substantial burden. The Veterans Diabetes Mellitus Working Group highlights these elements of the impact of diabetes in the VHA (Sullivan et al., 2007; Krein et al., 2000).

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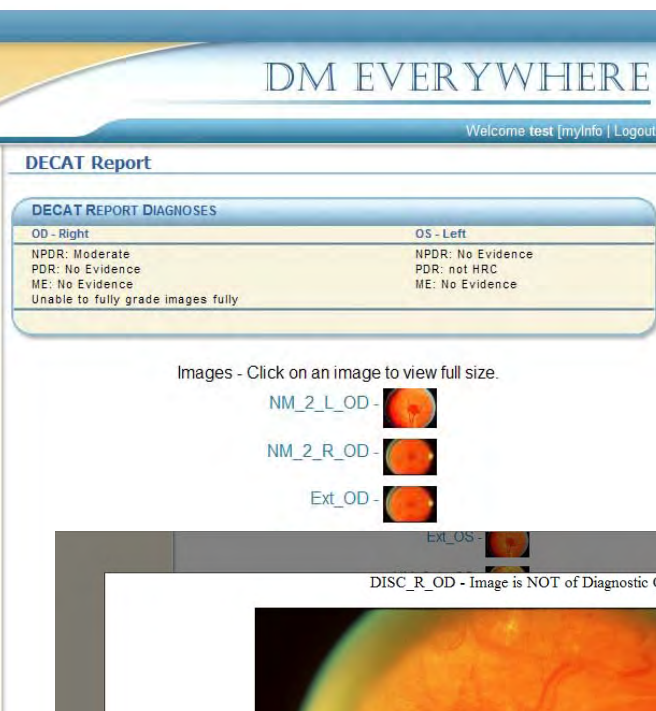
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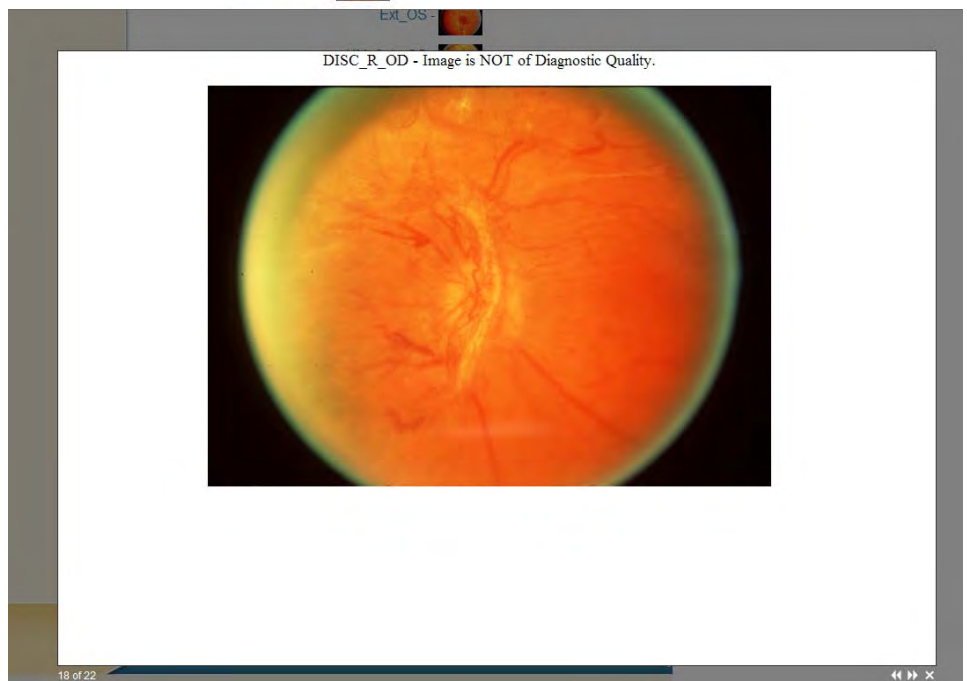
Attachment 1 Patient Portal Mockup



Home page will be customized for this project.



Patient uses will be able to see image diagnosis reports and click on images for larger view.



Attachment 2

Screen Shots of Educational Website

